510 (k) Summary of Safety and Effectiveness

Date Summary Prepared:	July 5, 2013
Submitter Information:	Spinal USA 2050 Executive Drive Pearl, MS 39208
Contact Name: Phone: Fax: E-mail:	Charles Vassallo 601-420-4244 601-420-5501 charles.vassallo@precisionspineinc.com
Device Trade Name:	Spinal USA Facet Screw System
Common Name:	Facet Screw System
Regulatory Number:	NA
Classification:	Unclassified
Product Code:	MRW

AUG 09 2013

INTENDED USE:

The Spinal USA Facet Screw System is intended to stabilize the spine as an aid to fusion by transfacet fixation. The device is indicated for posterior surgical treatment with or without bone graft, at single or multiple levels, of any or all of the following spinal levels L1 to S1 (inclusive): Spondylolisthesis, Spondylolysis, Pseudoarthrosis or failed previous fusions which are symptomatic: Degenerative Disc Disease (DDD) as defined by back pain of discogenic origin with degeneration of disc confirmed by history and radiographic studies and/or degenerative disease of the facets with instability.

DEVICE DESCRIPTION:

The Spinal USA Facet Screw System consists of a assortment of screws. Each are made of medical grade titanium alloy conforming to such standards as ASTM F-136 and/or ISO 5832-3. The screws will be provided non-sterile.

MECHANICAL TESTING:

The Facet Screw System was mechanically tested per ASTM F543 and ASTM F1264. The objective of the tests where to test the Facet Screw System using the following test methods:

- Axial Pullout
- Torque to Failure
- Static 3 - Point Bending
- Dynamic 3 – Point Bending

Conclusions of this testing demonstrated comparable mechanical performance to the predicate device tested in direct side by side testing. It further demonstrated strengths that exceed all physiological loads and accepted criteria along with spinal column through the facet joint with significant margin of safety provided. The Facet Screw System performed comparably to the commercially available predicate and demonstrated sufficient strength and fatigue resistance to stabilize the facet joint during fusion healing. Overall, the Facet Screw System performed well above the acceptance criteria and will adequately stabilize a fusion segment.

EQUIVALENT DEVICE:

Documentation was provided which demonstrated the Facet Screw System to be substantially equivalent to previously cleared devices. The substantial equivalence is based upon equivalence in intended use, indications, anatomic sites, performance and material of manufacture.

The overall design of the Facet Screw System consists of various sizes of screws. The screws are available in different diameters and lengths to accommodate patient anatomy and are substantially equivalent to the predicate devices.

PREDICATE DEVICE:

TranS1 Facet Screw, K073515

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 9, 2013

Mr. Charles Vassallo
Senior Director of Quality and Regulatory
Spinal United States of America
2050 Executive Drive
Pearl, Mississippi 39208

Re: K130863
Trade/Device Name: Facet Screw System
Regulatory Class: Unclassified
Product Code: MRW
Dated: July 11, 2013
Received: July 11, 2013

Dear Mr. Vassallo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130863

Device Name: Facet Screw System

Indications for Use:

The Spinal USA Facet Screw System is intended to stabilize the spine as an aid to fusion by transfacet fixation. The device is indicated for posterior surgical treatment with or without bone graft, at single or multiple levels, of any or all of the following spinal levels L1 to S1 (inclusive): Spondylolisthesis, Spondylolysis, Pseudoarthrosis or failed previous fusions which are symptomatic: Degenerative Disc Disease (DDD) as defined by back pain of discogenic origin with degeneration of disc confirmed by history and radiographic studies and/or degenerative disease of the facets with instability.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Colin O'Neill

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K130863